

May 11, 2005

Glenn S. Simon, Ph.D., DABT  
Rhodia Inc.  
5171 Glenwood Avenue  
Suite 402  
Raleigh, NC 27612

Dear Dr. Simon:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for BISCEP posted on the ChemRTK HPV Challenge Program Web site on March 30, 2004. I commend Rhodia Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Rhodia advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov).

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: M. E. Weber  
J. Willis

## **EPA Comments on Chemical RTK HPV Challenge Submission: BISCEP**

### **Summary of EPA Comments**

The sponsor, Rhodia Inc., submitted a test plan and robust summaries to EPA for BISCEP dated December 23, 2003. BISCEP is a mixture of 2-chloroethylphosphonic acid bis(2-chloroethyl) ester (55-70% w/w, BISCEP monomer, CAS No. 6294-34-4) and , 2-[[[(2-chloroethoxy)(2-chloroethyl)phosphinyl]-oxy]ethylphosphonic acid bis(2-chloroethyl) ester (35-40% w/w, BISCEP dimer, CAS No. 58823-09-9). EPA posted the submission on the ChemRTK HPV Challenge Web site on March 30, 2004.

EPA has reviewed this submission and reached the following conclusions:

1. General. The submitter needs to better identify the test substances in robust summaries. It is unclear what the various synonyms represent. The evaluation of several studies depends on this information.
2. Physicochemical Properties. Data for these endpoints may be adequate for the purposes of the HPV Challenge Program. However, to the extent the individual components are available, some additional testing may be needed.
3. Environmental Fate. EPA agrees with the test plan for these endpoints, except that EPA reserves judgement on the adequacy of the submitted biodegradation data pending receipt of more study details.
4. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program pending clarification of the test substances used.
5. Ecological Effects. EPA reserves judgement on the adequacy of all aquatic toxicity endpoints pending receipt of the stability-in-water test results and test substance clarification.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

### **EPA Comments on the BISCEP Challenge Submission**

#### **General**

The test plan implies indirectly that the BISCEP monomer and dimer occur only as components of the commercial BISCEP mixture. The test plan needs to be state explicitly whether either or both substances are ever available routinely or for commercial purposes.

The test substance identified in the robust summaries as MCTR-x (where x = various numbers) is not listed as a synonym for BISCEP. Since the batch analysis or characterization of these substances is not provided, it is unclear whether the test substance is the commercial mixture or other substance, such as the monomer. Therefore, EPA reserves judgement on most endpoints pending receipt of adequate identification of the test substance used.

## **Test Plan**

### **Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)**

Data for these endpoints are adequate for the purposes of the HPV Challenge Program, if the BISCEP monomer and dimer are not reasonably available. However, to the extent individual components are available for testing, melting point and water solubility testing are needed for monomer and dimer, and vapor pressure testing is needed for the monomer (the estimated value for the dimer does not reach the testing threshold).

### **Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)**

The photodegradation and fugacity data are adequate for the purposes of the HPV Challenge Program.

EPA agrees with the submitter's proposal for stability in water testing. The submitter needs to reevaluate the fugacity endpoint when the water stability data become available.

*Biodegradation.* EPA reserves judgement on the adequacy of the submitted biodegradation data pending receipt of essential study details. The submitter needs to clarify whether the "domestic sewage" used for the biodegradation study is "pure" sewage or the mineral nutrient medium inoculated with sewage, as well as clarify test substance identity.

### **Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)**

Although the studies for acute, repeated-dose, gene mutation, and developmental toxicity appear adequately performed for the purposes of the HPV Challenge Program, EPA reserves judgement on these endpoints pending receipt of adequate identification of the test substance used.

*Chromosomal Aberrations.* EPA agrees that testing for chromosomal aberrations is needed to address this endpoint but recommends an *in vitro* mammalian chromosome aberration test according to OECD TG 473 (in keeping with the policy stated in October 14, 1999 Letters to Manufacturers/Importers) instead of the proposed mammalian erythrocyte micronucleus study according to OECD TG 474, unless the known chemical properties preclude the *in vitro* testing.

*Reproductive Toxicity.* Although the submitter proposed testing for reproductive toxicity, it has provided an adequate developmental toxicity study and an evaluation of reproductive organs in the 13-week repeated-dose toxicity study. If EPA receives adequate test substance identification information, these available data will be sufficient to address this endpoint for the purposes of the HPV Challenge Program.

### **Ecological Effects (fish, invertebrates, and algae)**

EPA reserves judgement on adequacy of all aquatic toxicity endpoints pending receipt of the stability-in-water test results and adequate test substance identification.

## **Specific Comments on the Robust Summaries**

None.

## **Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.